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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/921,851	08/03/2001	Gary K. Michelson	101.0084-02000	8299
22882	7590	08/18/2005		
MARTIN & FERRARO, LLP 1557 LAKE O'PINES STREET, NE HARTVILLE, OH 44632			EXAMINER SNOW, BRUCE EDWARD	
			ART UNIT	PAPER NUMBER
			3738	
DATE MAILED: 08/18/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/921,851

Applicant(s)

MICHELSON, GARY K.

Examiner

Bruce E. Snow

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 May 2005.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 126-130, 207-210, 213-225 and 227-258 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 126-130, 207-210, 213-220 and 236-258 is/are allowed.
- 6) ☒ Claim(s) 221-225, 227-234 and 258 is/are rejected.
- 7) ☒ Claim(s) 235 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>09/09/05</u> <u>5/4/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's amendments and argues filed 5/04/05 have been fully considered. Regarding the double patenting rejection, applicant's arguments are not persuasive. Applicant must file a terminal disclaimer in both applications.

Regarding the rejection of claims 221-225, 227-234, and 258 under 35 U.S.C. 103(a) as being unpatentable over Aebi et al (6,482,233), applicant disagrees that Aebi et al teaches a facet opposite the direction of insertion which is described having an "angle B which may be preferably range from about 0 to about 30 degrees". It is the Examiner's position that this is only a **preferred** range within a larger range. The teaching "about 0" inherently includes negatives angle. The Examiner notes applicant's submission of the restriction requirement made in 09/457,228; it is unclear how this changes the teachings of Aebi et al wherein about zero would inherently include a negative and positive range.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Art Unit: 3738

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

All claims are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over all claims of copending Application No. 10/808,852. Although the conflicting claims are not identical, they are not patentably distinct from each other claiming the same method for forming an interbody spinal implant with the same claim limitations.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Allowable Subject Matter

(with the submission of proper terminal disclaimer)

Claims 126-130, 207-220, and 236-257 are allowed.

Claim 235 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 221-225, 227-234, and 258 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aebi et al (6,482,233).

Aebi et al teaches a spinal implant comprising bone engaging structures that are generally pyramid-shaped, as shown in figures 1 and 3, formed on the upper and lower surfaces of the implant. The engaging structures are slanted towards the anterior therefore having a forward (anterior) facing facet that is shorter than a rearward facing facet and said forward facing facet has a steeper slope; the structures further include side facets. Applicant claims the opposite of Aebi et al claiming the bone engaging structures slant rearward (posteriorly) producing a forward facet which is longer. However, both Aebi et al and applicant teach the bone engaging structures slant in a direction such to allow ease of insertion and to avoid retropulsion. See Aebi et al column 4, lines 30-34 and applicant's specification page 5, lines 5-9 and lines 15-19. It would have been obvious to one having ordinary skill in the art to have slanted the bone engaging structures of Aebi et al posteriorly such that the implant could be introduced posterior-laterally and/or resist movement in the direction towards the spinal cord when a surgeon deems it necessary. Note that Aebi et al teaches the steeper angled face can be "from about 0 to 30 degrees" which the Examiner interprets "about 0" to include negative angles. Therefore, both the forward facet and the rearward facet both have a negative inclination which produces a portion that extend outside the perimeter of a base portion or "said rearward facet terminating at a first location proximate the base, said rearward facet terminating at a second location proximate said forward facet, the first location being closer to the leading end of the implant than the second location (claim 221)."

Additionally, it would have been obvious to one having ordinary skill to have used any bone growth material known in the art or to have constructed the implant from any material known in the art for their known properties and characteristics.

Aebi et al fails to teach specific manufacturing steps such as casting, milling, grinding etc. Aebi et al does teach the implant is constructed of metal; see column 6, lines 30 et seq. It would have been obvious to one having ordinary skill in the art of metal working to use any of the claimed method of construction to make the spinal implant of Aebi et al because of their widely accepted use.

Many of applicant's dependent claims claim a wide range of limitations, for example, elements/materials/shapes/tools/etc which lack criticality in the specification, the use of any limitations in lieu of those used in the references solves no stated problem and produces no benefits and would have been an obvious matter of design choice for someone skilled in the art. Additionally, these limitations are well known in the prosthetic art and would have been obvious to one having ordinary skill.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

Art Unit: 3738

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E. Snow whose telephone number is (571) 272-4759. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

bes

A handwritten signature in black ink, appearing to be 'BS' followed by a stylized flourish.

BRUCE SNOW
PRIMARY EXAMINER